SECTION 5
510(K) SUMMARY

510(K) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01545
Telephone: 508-683-4454
Fax: 508-683-5939

Contact: Virginia Carr
Regulatory Affairs Specialist
Date Prepared: August 31, 2007

DEC 1 4 2007

2. Device:

Trade Name: TTP Jejunostomy Tube Kit
Common Name: Jejunostomy Tube
Classification Name: Gastrointestinal Tubes and Accessories
Regulation Number: 876.5980
Product Code: KNT
Classification: Class II

3. Predicate Device(s):

- Boston Scientific Corporation's TTP Jejunostomy Tube Kit, K971906
- Wilson-Cook Medical's Nasal Jejunal Feeding Tube, Nasal Feeding Tube with Flaps, K042303

Both predicates are class II devices per 21 CFR 878.3610

4. Device Description:

The proposed TTP Jejunostomy Tube consists of a three-port device designed to be placed through a Boston Scientific gastrostomy tube to provide enteral access for decompression and delivery of nutrition and/or medication. The TTP Jejunostomy Tube is available in two tip configurations (pigtail and bent tip) and may be placed by either a pullwire (pull) or guidewire (push) technique. The proposed device is available within a kit which contains the following: a stiffening cannula, a guidewire, lubricating jelly, gauze, a double barbed fitting (attached to stiffening cannula), and a cable tie.

5. Intended Use:

The TTP Jejunostomy Tube Kit is intended to provide enteral access for decompression and delivery of nutrition and/or medication.

6. Technological Characteristics:

The proposed TTP Jejunostomy Tube Kit has the identical technological characteristics (materials, construction, manufacturing processes) as the currently marketed TTP Jejunostomy Tube Kit (K971906).

7. Performance Data:

As this is a request to clarify the indication the performance testing presented in K971906 was not repeated.

8. Conclusion:

Boston Scientific Corporation has demonstrated that the proposed TTP Jejunostomy Tube Kit is substantially equivalent to Boston Scientific Corporation's currently marketed TTP Jejunostomy Tube Kit (K971906) and, in terms of the proposed indication, to the Boston Scientific Corporation's TTP Jejunostomy Tube Kit (K971906) and Wilson-Cook Medical's Nasal Jejunal Feeding Tube and Nasal Feeding Tube with Flaps (K043203).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 4 2007

Ms. Jennifer Kimball
Regulatory Affairs Manager
Boston Scientific Corporation
100 Boston Scientific Way
MARLBOROUGH MA 01752-1234

Re: K072476
Trade/Device Name: Through the PEG (TTP) Jejunostomy Tube Kit
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: November 27, 2007
Received: November 28, 2007

Dear Ms. Kimball:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

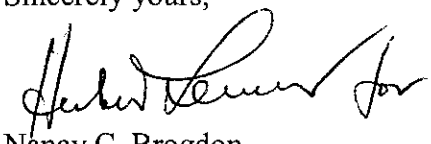
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh.dsma/dsmamain.html.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

K072476

SECTION 4
INDICATIONS FOR USE STATEMENT

Indications for Use:

510(k) Number (if known): **To Be Determined**

Device Name: **Through the PEG (TTP) Jejunostomy Tube Kit**

Indications For Use:

The TTP Jejunostomy Tube Kit is intended to provide enteral access for decompression and delivery of nutrition and/or medication.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072476